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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/639,057	08/11/2003	Donald J. McMichael	19,480	6758

23556 7590 04/18/2006

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EXAMINER

WITCZAK, CATHERINE

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/639,057	MCMICHAEL, DONALD J.	
	Examiner	Art Unit	
	Catherine N. Witczak	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 24-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 24-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/18/09; 4/13/09(2); 10/21/09</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Species 1 (Figure 2) in the reply filed on March 15, 2006 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 11-22 and 24-32 rejected under 35 U.S.C. 102(b) as being anticipated by Foster et al (US 5,997,546).

Claims 11 and 12: Foster et al disclose in Figure 5 an expandable member (118) having a first (134) and second (132) end; an elongate shaft (126) having a wall with an outer surface, a recess (180), and a first thickness proximal the recess (180) and a second thickness in the recess (180) (column 5, line 66 – column 6, line 14) such that the first end (134) of the expandable member (118) and the second thickness of the wall in the recess is no greater than the first thickness of the wall (column 6, lines 5-14); and a first (168) and second (156) lumen for fluid communication with the expandable member (118).

Claims 13 - 19: Foster et al disclose in Figure 5 an expandable member (118) having a first (134) and second (132) end; an elongate shaft (126) having a wall with an outer surface, a recess (180), and a first diameter proximal the recess (180) and a second diameter in the recess (180) (column 5, line 66 – column

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6, line 14) such that the first end (134) of the expandable member (118) and the second diameter of the shaft is no greater than the first diameter of the shaft (column 6, lines 5-14); and a first (168) and second (156) lumen for fluid communication with the expandable member (118).

Claims 20: Foster et al disclose in Figure 5 a head (114) having two openings (140 and 148) through which fluid may pass; an elongate shaft (126) having a first (168) and second (156) lumen for communication with the two openings (140 and 148) and an exterior, interior and a recess (180); a sleeve (118) having a first (134) and second (132) end; wherein a portion of the first end (134) of the sleeve (118) is attached in the recess (180) such that the outer diameter of the shaft at the recess plus at least a portion of the thickness of the first end (134) of the sleeve (118) attached in the recess (180) is less than the outer diameter of the shaft proximal the recess (column 6, lines 5-14).

Claim 21: Foster et al disclose in Figure 5 an expandable cavity formed between the sleeve (118) and the shaft (126).

Claim 22: Foster et al disclose in Figure 5 a portion of the sleeve (118) attached to the exterior of the shaft (132) and a portion of the sleeve (134) attached to the interior of the shaft.

Claim 24: Foster et al disclose in Figure 5 the catheter comprising a tip (130) attached to the shaft (126).

Claim 25: Foster et al disclose in Figure 5 a portion of the sleeve (118) being attached to the exterior of the catheter shaft (132) and a portion (134) being attached to the tip (130).

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Claims 26, 31, and 32: Foster et al disclose in Figure 5 a shaft (126) having a first and second end and a first (168) and second (156) lumen for fluid communication; and an expandable member (118) having a first (134) and second (132) end. Foster et al further disclose in column 6, lines 1-14 that the diameter of the recess is slightly greater in depth than the thickness of the distal end.

Claim 27: Foster et al disclose in column 5, lines 20-24 that the ends of the expandable members form cuffs.

Claim 28: Foster et al disclose in Figure 5 a portion of the second end of the sleeve (134) attached to a second end of the shaft (126a).

Claim 29: Foster et al disclose in Figure 5 the catheter comprising a tip (130) attached to the shaft (126).

Claim 30: Foster et al disclose in Figure 5 the sleeve (118) attached to the interior of the tip (130) and the exterior of the shaft (126).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al as modified by Miller et al (US 2002/0198492).

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Claim 1: Foster et al disclose in Figure 5 a shaft (126) having a first and second end and a first (168) and second (156) lumen for fluid communication; and an expandable member (118) having a first (134) and second (132) end.

Foster et al disclose the claimed invention except for the exterior surface having a recess wherein a portion of the first end of the expandable member is attached. Miller et al teach that it is known to use a catheter comprising an exterior surface having a recess wherein a portion of the first end of the expandable member is attached in paragraph 0011. Miller et al do not explicitly state why a catheter comprising an exterior surface having a recess wherein a portion of the first end of the expandable member is attached is used, but it appears that it is used so that the catheter can be more easily inserted and removed from lumens. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Foster et al with a catheter comprising an exterior surface having a recess wherein a portion of the first end of the expandable member is attached as taught by Miller et al since such a modification would provide the system with a catheter that is more easily inserted and removed from lumens.

Claims 2 and 3: Foster et al disclose in Figure 5 the catheter having a second recess (180) in the interior surface into which a portion of the second end of the expandable member (118) is inserted.

Claim 4: Foster et al disclose in Figure 5 the catheter comprising a tip (130) attached to the shaft (126).

Claim 5: Foster et al disclose in Figure 5 the tip (130) having a second recess (180) in the interior surface into which a portion of the second end of the expandable member (118) is inserted.

Claim 6: Foster et al disclose in Figure 5 the tip (130) being part of the shaft (126).

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Claim 7: Foster et al disclose in Figure 5 the second end of the expandable member (118) being attached to the tip (130).

Claim 8: Foster et al disclose in column 5, lines 20-24 that the ends of the expandable member form a cuff.

Claim 9: Foster et al disclose in column 5, lines 43-53 a catheter comprising a unitary component having a tip integrally formed with the expandable member wherein the tip is attached to the second end of the shaft.

Claim 10: Foster discloses in Figure 5 the expandable member being a balloon (118).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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C
KEVIN SIRMONS
PRIMARY EXAMINER

Kevin C. Simons